FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

November 27, 2017

Robert DiMaggio
IronMag Labs, LLC
1860 Whitney Mesa Dr. #120
Henderson, Nevada 89014

Dear Mr. DiMaggio:

We received your letter dated October 30, 2017, written in response to Warning Letter 494623 dated October 27, 2017, describing voluntary corrections to the violations noted in the Warning Letter. Your response states that you have not manufactured "Super DMZ 4.0" or any other products containing Ostarine since 2015. Additionally, you describe that no supplement retailers or distributors have any product remaining. However, as of November 9, 2017, we continue to find "Super DMZ 4.0" for sale on distributor websites.

We appreciate your willingness to comply with the charges set forth in the Warning Letter. We also request the following additional information:

1. The name(s) and address(es) of the manufacturer(s) and/or supplier(s) of the product listed in the Warning Letter. Please provide the latest shipping records, such as bill of ladings and U.S. Customs and Border Protection entry documentation (e.g., CBP Form 3461).
2. Plans to ensure the product listed in the Warning Letter is no longer for sale in interstate commerce. This includes the product sold directly by your firm, as well as all distributors and other retailers.
3. Plans for what you intend to do with the remaining violative product in your possession.

Send your reply to:

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV
United States Food and Drug Administration
19701 Fairchild
Irvine, California 92612-2506

We remind you that the violations cited in the Warning Letter are not intended to be an all-inclusive statement of violations that exist in connection with your products. Please review all products to ensure that they meet the requirements of the Food, Drug, and Cosmetic Act. In particular, ensure all ingredients in your "dietary supplement" products can be marketed lawfully.

Note that the effectiveness and proper implementation of your firm's corrective and preventive actions may be verified upon FDA inspection.

If you have any questions regarding any issues in this letter, please contact Maria P. Kelly-Doggett, Compliance Officer, via email to maria.kelly-doggett@fda.hhs.gov or by phone at (425) 302-0427 and reference unique identifier **494623.**

Sincerely,

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV

SP: mpk

Bcc: (Internal) (Send via email)
Maria Kelly-Doggett, Compliance Officer, ORA/DPQO IV/OMPTO

CMS No.: 494623